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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/042,460 03/16/98 MORIN

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EXAMINER

GREGORY F. EINHORN
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111

KAUSHAL, S

ART UNIT	PAPER NUMBER
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1633

DATE MAILED:

07/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/042,460	Applicant(s) MORIN et al
Examiner SUMESH KAUSHAL	Group Art Unit 1633



Responsive to communication(s) filed on Feb 14, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 20-30 is/are pending in the application.
Of the above, claim(s) 29 and 30 is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 20-28 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The applicant's response filed on Paper No. 18, 02/14/00 has been fully considered. Claims 1-4, 10-14 and 17-19 are canceled. Newly filed claims 20-30 are entered and are pending in this application.

Newly submitted claims 29-30 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The instant claims reads on a non elected invention which encompasses host cells wherein the cells are part of an animal (see applicant's election on Paper No. 12, 09/20/00).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

1. Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and for the reasons of record set forth in Official action mailed 10/13/99.

Applicant's arguments filed on Paper No. 18, 02/14/00 have been fully considered but they are not persuasive. The applicant argues that the specification describes the structure and function of the isolated, purified or recombinant polynucleotide encoding mTERT protein that has at least 90% sequence identity to SEQ ID NO:2 and has telomerase activity (response page 4, para.4 line 10).

However, the applicant fails to point out where in the specification it is taught that any protein with 90% sequence identity has any telomerase activity. The instant claims are drawn to an isolated nucleic acid molecule encoding mTERT and its allelic variants with at least 90% sequence identity to SEQ ID NO:2. There is no description of mutational sites that exist in nature and there is no description of how the structure of mTERT relates to the structure of different alleles. In addition, according to the standard definition of allelic variants the genus include members that would be expected to have widely divergent functional properties. The general knowledge in the art concerning telomerase is that telomerase-complex consists of TERT protein, RNA component and other TRT associated proteins. Furthermore, TERT protein consists of several conserved motifs that are required for the telomerase activity (Lundblad, PNAS 95:8415-8416, 1998). The specification as filed fails to identify the common attributes of individual alleles other than SEQ ID NO: 1 and 2. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claims 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which

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it pertains, or with which it is most nearly connected, to make and/or use the invention and for the reasons of record set forth in Official action mailed 10/13/99.

2. Applicant's arguments filed 04/15/00 have been fully considered but they are not persuasive because applicant fails to response to the rejections set forth in previous Official action (pages 5-8).

The instant claims are drawn to an isolated nucleic acid encoding a mouse TERT protein which has 90% sequence identity to SEQ ID NO: 2 and has telomerase activity. The specification as filed fails to disclose all polynucleotide sequences that has 90% sequence identity to SEQ ID NO: 2 and has telomerase like activity. It is known in the art that "telomerase complex" consists of telomerase protein (TERT), telomerase RNA moiety and telomerase associated proteins which are essential for the maintenance of telomere length (Lundblad, PNAS 95:8415-8416, 1998, page 8415, col.1 para.2, page 8416 col.1, para 2-3). Furthermore, it is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted. For example, mutation of key residues in TERT gene are know to abolish the telomerase activity (Lundblad, PNAS 95:8415-8416, 1998, page 8415, col.1 para.2, page 8416 col.1, para 2-3). Consequently, excessive trial and error experimentation would be required to identify the necessary nucleic acid sequence derivatives encoding a biologically active polypeptide with an amino acid sequence differing from SEQ ID NO: 2, since the amino acid sequence of such polypeptide could not be predicted *a priori*.

3. Applicant's arguments filed 02/14/00 page 5-6 have been fully considered but they are not persuasive. Applicant argues that the specification is enabled for making knockout cells that lacks mTERT gene which are deficient in telomerase activity.

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However, the specification as filed fails to disclose a mouse cell in which endogenous mTERT gene has been mutated by any recombinant means and the cell is deficient in telomerase activity. The specification articulates that the mTERT gene can be knocked out using conventional techniques usually involving homologous recombination (page 112, line 4-12). However, the phenotype of targeted mutations by a homologous recombination have not always been as predicted from the knowledge of the nature of the gene product and its pattern of expression (Rossant et al , Phil. Trans. R. Soc Lond. B. 339:137-254, 1993; page 71 col.2 par.2). Thus, in view of unpredictable nature of homologous recombination and lack of specific guidance in the specification, the skilled artisan at the time of filing would be unable to use the claimed invention.

Thus, in view of lack of specific guidance in the specification, the skilled artisan at the time of filing would be unable to use the claimed invention, without an excessive and undue amount of experimentation. The quantity of experimentation required would include the functional characterization of all nucleotide sequence that has 99% identity to SEQ ID NO 2, and the role of deduced polynucleotide sequences as a telomerase activity. In addition, undue experimentation required would include making genetic construct to knock out mTERT gene, and transfection and cloning of mouse cells lacking endogenous mTERT gene wherein the cell lacks telomerase activity.

Conclusion

No claims are allowed.

Claims 20-28 are free of prior art. The art at the time of filing does not teach or suggest an isolated polynucleotides encoding mTERT protein that has telomerase catalytic activity.

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4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned as (703) 308-2035. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

S. Kaushal, AU 1633

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600